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National Organic Standards Board Handling Sub Committee Petitioned Material Proposal Sulfuric Acid

January 9, 2013

Summary of Proposed Action:

The petition is for the listing of sulfuric acid on 205.605(b) for use as a processing aid in the production of seaweed extract. Sulfuric acid is used as a pH adjuster in the extraction water for the production of seaweed extracts, particularly a class of seaweed extracts called fucoidans, which are largely used as ingredients in dietary supplements.

For a number of reasons, the Handling Subcommittee recommends that sulfuric acid not be added to the national list as petitioned:

- The redaction of substantial amounts of confidential business information (CBI) from the petition makes it impossible to evaluate the use of sulfuric acid in the manufacturing process, and impossible to establish whether the resulting seaweed extract undergoes sufficient chemical change as to render it a synthetic substance.
- The petition and TR fail to demonstrate the essentiality of this substance in the production of organic food, or the absence of viable alternatives. The petition provides little economic data or market narrative to demonstrate that this substance might play a compelling role in the production of organic products, and the redacted CBI makes it impossible to even understand how sulfuric acid is used in seaweed extract production.
- The TR clearly documents negative environmental impacts of the production of this substance, suggests negative health effects in its production and industrial use, and overwhelmingly demonstrates the substance's incompatibility with a system of organic agriculture.

Evaluation Criteria				
(Applicability noted for each category; Documentation attached)	Criteria	Satisfie	d?	
Impact on Humans and Environment	☐ Yes	X No	\square N/A	
2. Essential & Availability Criteria	☐ Yes	X No	□ N/A	
3. Compatibility & Consistency	☐ Yes	X No	□ N/A	
 Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606) 	☐ Yes	□ No	X N/A	
Substance Fails Criteria Category: [1, 2 and 3] Comments:				
Proposed Annotation (if any):				
Basis for annotation: \Box To meet criteria above \Box Other regulator Notes:	ory criteria	☐ Citation	on	
Recommended Committee Action & Vote, including classification red	ommendat	ion (state	e actual mo	tion):

Classification Motion: Motion to classify sulfuric acid (CAS 7664-93-9) as petitioned as synthetic: Motion by: Joe Dickson Seconded by: John Foster

No further discussion

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: List sulfuric acid (CAS 7664-93-9) as petitioned on 205.605(b)

Motion by: Joe Dickson Seconded by: Tracy Favre No further discussion

Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Crops		Agricultural		Allowed ¹	
Livestock		Non-synthetic		Prohibited ²	
Handling	X	Synthetic	X	Rejected ³	Χ
No restriction		Commercial unavailable as organic		Deferred ⁴	

¹Substance voted to be added as "allowed" on National List to § 205. with Annotation (if any):

If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

John Foster, Subcommittee Chair January 9, 2013

²Substance to be added as "prohibited" on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

³Substance was rejected by vote for amending National List to § 205.605(b). Describe why material was rejected:

⁴Substance was recommended to be deferred because

Category 1. Adverse impacts on humans or the environment? Substance: Sulfuric Acid

regulatory agency; other) 1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2] 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3] 3. Is the substance harmful to the environment and biodiversity? [§6517(1)(A)(i)(517(C)(2)(A))] 4. Does the substance contain List 1, 2 or 3 merts? [§6518 m.1] 6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5] 7. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5] 9. Is there undesirable persistence or concentration of the material or its breakdown products in environment? [§6518 m.2] 9. Is there undesirable persistence or concentration of the material or its breakdown products in environment? [§6518 m.2] 11. Is there an adverse effect on human health? [§6517 c (1)(A)(i)): 6517 c (2)(A)i; §6518 m.4] 11. Is there an adverse effect on human health? [§6518 m.4] 11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3] 12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.3] 13. Does the substance contain residues of heavy metals or other contaminants in interaction in formation to information to startly hill the residue of the residues of heavy metals or other contaminants in interaction information to startly hill the residues of the residues of the material are persistence.		tegory 1. Adverse impacts on humans o				
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b.5]	zinc, arsenic, mercury, lead, and selenium) have been reported in manufactured sulfuric acid product, no information was found to indicate the levels of these substances in sulfuric acid used for pH adjustment. Therefore it is unknown if these contaminants are in excess of FDA tolerances in sulfuric acid.
	" – TR Lines 318-321

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance: Sulfuric Acid

	Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1.	Is the substance formulated or manufactured by a chemical process? [6502 (21)]	х			TR lines 262-263
2.	Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		
	Is the substance created by naturally occurring biological processes? [6502 (21)]		X		
4.	Is there a natural source of the substance? [§205.600 b.1]		х		TR lines 268-269
5.	Is there an organic substitute? [§205.600 b.1]		X		Because the manufacturing process is redacted from the petition, it is impossible to determine whether the use of other pH adjusters such as citric or lactic acid is viable or appropriate. TR lines 392-398
6.	Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		Х		TR lines 392-398
7.	Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			х	Again, the petition and TR do not provide sufficient information to determine the necessity of the material, or if the resulting seaweed extract has undergone sufficient chemical change to be rendered synthetic.
8.	Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		Х		
9.	Is there any alternative substances? [§6518 m.6]			Х	
10.	Is there another practice that would make the substance unnecessary? [§6518 m.6]			Х	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 3. Is the substance compatible with organic production practices? Substance: Sulfuric Acid

	Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1.	Is the substance compatible with organic handling? [§205.600 b.2]		х		regulatery agency, cancely
2.	Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		Х		
3.	Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		Х		
	Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			Х	CBI redacted from petition makes it impossible to establish how the substance impacts the food.
5.	Is the primary use as a preservative? [§205.600 b.4]		X		It is not clear that the petitioned use is as a preservative per se, but the TR notes a number of preservative uses of the substance (lines 288-298)
6.	Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		х		TR line 305
7.	Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			х	
	 a. copper and sulfur compounds; 				
-	b. toxins derived from bacteria;			X	
	 c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals? 			Х	
	d. livestock parasiticides and medicines?			Х	
	e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			Х	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance Name: Sulfuric Acid

	Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1.	Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			х	
2.	Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	
3.	Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate guality to fulfill an essential function in a system of organic handling?			x	
4.	Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate <u>quantity</u> to fulfill an essential function in a system of organic handling?			x	
5.	Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			х	
	 Regions of production (including factors such as climate and number of regions); 				
	 b. Number of suppliers and amount produced; 			Х	
	 c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; 			X	
	d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
	e. Are there other issues which may present a challenge to a consistent supply?			Х	